

July 30, 2003

Marianne L. Horinko  
Acting Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Bldg. (1101A)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460



Re: Comments on the HPV test plans and robust summaries for crude BHMT and sec-butyl urea, submitted by E.I. DuPont de Nemours and Co.

Dear Ms. Horinko:

The following comments are on DuPont's test plans for crude BHMT and sec-butyl urea. These comments are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the US, the Doris Day Animal League, and Earth Island Institute. These animal protection, environmental, and health advocacy organizations have a combined membership of more than ten million Americans.

In these two test plans, a great deal of data are presented from previous studies carried out by DuPont itself, as well as by other corporations and organizations. On the basis of these data, DuPont has appropriately concluded that no additional testing is called for under the HPV program.

With respect to crude BHMT, DuPont has decided not to carry out an acute aquatic toxicity study because sufficient information about fish toxicity is already available for BHMT (i.e., refined BHMT). As the test plan correctly states: "Because BHMT is the primary component of crude BHMT, it is reasonable to conclude that the crude BHMT would behave similarly to BHMT in the areas where data gaps are evident for the crude material" (p. 6). This complies with the EPA's December 2000 *Federal Register* notice and its October 1999 letter, stating that: "Participants shall maximize the use of scientifically appropriate categories of related chemicals and structure activity relationships" (<http://www.epa.gov/chemrtk/ceoltr2.htm>).

The EPA disagrees with DuPont's conclusion that no new mammalian testing is needed. However, the argument against the conduct of a fish test applies similarly to additional mammalian endpoints. We therefore urge DuPont to make a further careful search of the databases to ascertain whether data exist on the developmental and reproductive toxicity of refined BHMT before it makes any decision as to whether it will carry out new testing according to OECD test guideline 421, as requested by the EPA in its comments on DuPont's test plan.

With respect to sec-butyl urea, we agree that sufficient acute fish toxicity and mammalian development toxicity are already available and no further aquatic or developmental studies can be justified. We also agree that the status of sec-butyl urea as a closed-system intermediate renders mammalian repeat-dose and reproductive toxicity studies unnecessary. Environmental Defense, in its comments on the test plan, maintains that the data provided are unacceptable, and

that a number of additional animal tests are needed. However, the issues raised by Environmental Defense could be overcome if DuPont were simply to submit a more detailed discussion regarding the specific tests.

Please contact me with any questions or concerns at [JessicaS@peta.org](mailto:JessicaS@peta.org) or 757-622-7382, ext. 1304.

Sincerely,

Jessica Sandler, MHS  
Federal Agency Liaison  
People for the Ethical Treatment of Animals

Richard Thornhill, PhD  
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PETA Research and Education Foundation